



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Zimmer, Incorporated
Mr. Stephen H. McKelvey
Senior Project Manager, Trauma Regulatory Affairs
P.O. BOX 708
Warsaw, Indiana 46581

February 6, 2015

Re: K143618

Trade/Device Name: Zimmer Kirschner wires and Steinmann pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, JDW
Dated: December 18, 2014
Received: December 19, 2014

Dear Mr. Stephen McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143618

Device Name

Zimmer Kirschner wires and Steinmann pins

Indications for Use (Describe)

Kirschner wires (K-Wires) and Steinmann pins are used for fixation of bone fractures, bone reconstruction, as guide pins for insertion of other implants, or to be implanted through the skin so that traction may be applied to the skeletal system. The pins and wires may be used in the threaded or unthreaded form depending upon the desired application.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Sponsor: Zimmer, Inc.
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Contact Person: Stephen H. McKelvey
Senior Project Manager, Trauma Regulatory Affairs
Telephone: (574) 372-4944
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Date: 12/18/2014

Trade Name: Zimmer Kirschner Wires and Steinmann Pins,

Common Name: Kirschner Wires and Steinmann Pins

Classification Names and References: Pin, Fixation, Smooth (HTY) and Pin, Fixation, Threaded (JDW) – both per 21 § CFR 888.3040, Smooth or threaded metallic bone fixation faster

Classification Panel: Orthopedics/87

Predicate Device(s): Kirschner Medical Corp., Kirschner Wire and Steinman Pins (K831005 - cleared 05/18/1983)

Purpose and Device Description: Zimmer Kirschner Wires and Steinmann Pins are used for fracture stabilization during the healing process. These wires are available in multiple diameters and lengths and threaded/unthreaded (smooth) versions.

Intended Use: Kirschner wires (K-Wires) and Steinmann pins are used for fixation of bone fractures, bone reconstruction, as guide pins for insertion of other implants, or to be implanted through the skin so that traction may be applied to the skeletal system. The pins and wires may be used in the threaded or unthreaded form depending upon the desired application.

Comparison to Predicate Device: The Zimmer Kirschner Wires and Steinmann Pins are identical in intended use and similar in basic shape, materials and performance characteristics to the predicate devices. The subject devices are provided sterile or non-sterile.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- Biocompatibility - Biocompatibility testing on the Pins and Wires materials was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR § 58). All testing passed.
- The Zimmer subject devices were considered for conformance to dimensional and material mechanical property standards ASTM F366 -10 and ISO 5838-1. All items in the scope were in conformance with those standards and are therefore substantially equivalent to the predicate devices.

Conclusions: The data presented in this submission demonstrates that the subject device is substantially equivalent to the predicate devices.

Clinical Performance and Conclusions:

- Clinical data and conclusions were not needed for these devices.